

DT12 Rec'd PCT/PTO 06 DEC 2004

**WHAT WE CLAIM IS:**

1. A process for administering to an animal at least three progressively increasing doses of one or more biologically active agents which are released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
2. A process as claimed in claim 1 wherein said one or more biologically active agents are selected from the list of antibiotics, anthelmintics, peptides, proteins, carbohydrates, DNA, RNA, hormones, neutraceuticals, vitamins, trace-elements, immunising agents or any combination thereof.
3. A process as claimed in either claim 1 of claim 2 wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.
4. A process as claimed in any one of claims 1 to 3 wherein the progressively increasing doses comprise sequentially doubling doses of biologically active agents, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.
5. A process as claimed in any one of claims 1 to 4 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from hours, days, weeks or months or any combination thereof.
6. A process as claimed in any one of claims 1 to 5 wherein said one or more biologically active agents is an immunising agent and wherein said process comprises the administration to said animal of progressively increasing doses of one or more immunising agents which are released over a predetermined

period of time from a delivery means which is administered to an animal on a single occasion.

7. A process as claimed in claim 6 wherein said one or more immunising agents comprise an antigen or combination of antigens.
8. A process as claimed in claim 6 or claim 7 wherein said one or more immunising agents comprise a vaccine or combination of vaccines.
9. A process as claimed in any one of claims 6 to 8 wherein said one or more immunising agents are selected from molecules that will induce protective immunity against a disease causing organism, or functional immunity or any combination thereof.
10. A process as claimed in any one of claims 6 to 9 wherein the progressively increasing doses of said one or more immunising agents are in the range of from 0.1  $\mu\text{g}$  to 1000  $\mu\text{g}$ .
11. A process as claimed in any one of claims 6 to 10 wherein the delivery means comprises an immunising agent delivery composition which comprises means to enable progressively increasing doses of one or more immunising agents to be released over a predetermined period of time therefrom, when said delivery means is administered to an animal on a single occasion.
12. A biologically active agent delivery composition comprising one or more biologically active agents whereby said composition comprises means to enable at least three progressively increasing doses of said one or more biologically active agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
13. A biologically active agent delivery composition as claimed in claim 12

25. A biologically active agent delivery composition as claimed in claim 24 wherein the administration of the delivery composition takes place shortly after birth of an animal, or when maternally-derived antibody has decreased sufficiently for the young animal to be able to respond to the vaccination, and provides immunity without the need for further booster administration.
26. A delivery means for use in a process as described in any one of claims 1 to 11 wherein the delivery composition is located within comprising a multi-compartmental capsule containing progressively increasing doses of one or more biologically active agents within the compartments, said delivery means comprising an outer wall made of a biodegradable substance which degrades over a pre-set period of time to release the smallest dose of biologically active agents, and one or more inner compartmental walls made of the same or different material that degrade over a longer period of time to release progressively increasing pulses of the biologically active agents
27. A delivery means as claimed in claim 26 wherein the biodegradable material of the outer wall is be selected from the group comprising cholesterol/lecithin, polylactide and/or polyglycolide copolymers, one or more of a number of cellulose polymers, polyacrylic acid, polymethylmethacrylate, cross-linked polyacrylic acid, polycaprolactone, polyvinylpyrrolidone, polyvinylalcohol, polyethylene glycol, agarose, DEAB dextran microspheres, starch microspheres and/or albumin microspheres or gelatine microspheres or any combination thereof.
28. A delivery means as claimed in claim 26 or claim 27 wherein the pre-set period of time within which the outer wall and inner compartmental walls degrade may be selected from hours, days, weeks or months.
29. A process substantially as described herein with reference to and as illustrated

by the accompanying description and drawings.

30. A biologically active agent delivery composition substantially as described herein with reference to and as illustrated by the accompanying description and drawings.